

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/777,018	02/05/2001	Roger N. Hastings	5236-000215	5479	
7590 07/27/2005			EXAMINER		
Harness, Dickey & Pierce			RAGONESE, ANDREA M		
Suite 400	•				
7700 Bonhomme			ART UNIT	PAPER NUMBER	
St. Louis, MO 63105			3743	3743	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)				
Office Action Summary		09/777,0	18	HASTINGS ET AL.				
		Examine	r	Art Unit				
	•	Andrea M	l. Ragonese	3743				
Period fo	The MAILING DATE of this commun or Reply	ication appears on the	e cover sheet with the	correspondence addres	S			
THE - Exte after - If the - If NC - Failt Any	ORTENED STATUTORY PERIOD F MAILING DATE OF THIS COMMUN nsions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this comn of period for reply specified above is less than thirty (3) period for reply is specified above, the maximum st are to reply within the set or extended period for reply reply received by the Office later than three months a ed patent term adjustment. See 37 CFR 1.704(b).	ICATION. of 37 CFR 1.136(a). In no ev nunication. 0) days, a reply within the stal attutory period will apply and w will, by statute, cause the app	rent, however, may a reply be tutory minimum of thirty (30) or vill expire SIX (6) MONTHS fro lication to become ABANDO	timely filed lays will be considered timely. om the mailing date of this commu NED (35 U.S.C. § 133).	nication.			
Status								
1) 又	Responsive to communication(s) file	ed on <i>11 May 2005</i> .						
2a)□	This action is FINAL . 2b) This action is non-final.							
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims							
5)□ 6)⊠ 7)⊠	Claim(s) 34-42 is/are pending in the 4a) Of the above claim(s) is/a Claim(s) is/are allowed. Claim(s) 34-42 is/are rejected. Claim(s) 34-42 is/are objected to. Claim(s) are subject to restrict	re withdrawn from cc						
Applicat	ion Papers							
9)	The specification is objected to by th	e Examiner.						
10)	The drawing(s) filed on is/are	a) accepted or b)□ objected to by th	e Examiner.				
	Applicant may not request that any obje	ction to the drawing(s)	be held in abeyance. S	See 37 CFR 1.85(a).				
11)	Replacement drawing sheet(s) including The oath or declaration is objected to	•	- · ·	-	, ,			
Priority	under 35 U.S.C. § 119							
a)	Acknowledgment is made of a claim All b) Some * c) None of: 1. Certified copies of the priority 2. Certified copies of the priority 3. Copies of the certified copies application from the Internation	documents have bee documents have bee of the priority docum anal Bureau (PCT Ru	en received. en received in Applic ents have been rece le 17.2(a)).	ation No ived in this National Stag	ge			
Attachmer	, ,		4) Intension Surren	on (PTO 412)				
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (F	PTO-948)	4) Interview Summa Paper No(s)/Mail	Date				
3) Infor	mation Disclosure Statement(s) (PTO-1449 or er No(s)/Mail Date		5) Notice of Informa 6) Other:	l Patent Application (PTO-152	.)			

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2005 has been entered.

Response to Amendment

2. The amendment filed on May 11, 2005 has been entered. Examiner acknowledges that claims 34, 35 and 39 have been amended. Subsequently, claims 34-42 are under consideration.

Response to Arguments

3. Applicant's arguments with respect to **claims 34-42** have been considered but are most in view of the new ground(s) of rejection.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA)

Application/Control Number: 09/777,018

Art Unit: 3743

1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 34-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7 and 20 of U.S. Patent No. 6,911,026. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations of the same subject matter.

Claim Objections

6. **Claims 34-42** are objected to because of the following informalities. Appropriate correction is required.

In claims 34, 35 and 39, —end— should be added after "proximal" in line 2.

In claims 34 and 35, "end is" should be deleted and —ends are— inserted therefor in line 9.

Application/Control Number: 09/777,018 Page 4

Art Unit: 3743

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Application/Control Number: 09/777,018

Art Unit: 3743

10. Claims 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponzi (US 5,964,757) in view of Nevo (US 6,594,517 B1).

Regarding claims 34 and 35, Ponzi discloses a device comrprsing:

a catheter 12 having a proximal end and distal end and a lumen 18 therebetween;

a support structure 19/36/14 in the lumen 18 adjacent the distal end;

one or more energy/optical conduits (such as **46**, etc.) in the catheter **12**, each having a distal end supported by the support structure **19/36**; and

one or more magnet members (such as **72** with **36** and **38**) disposed in the distal end of the catheter **12** (recited throughout the specification with emphasis on column 9), as shown in Figures 2A-8.

Ponzi discloses an apparatus comprising all the limitations recited in **claims 34** and **35**, with the exception of a rotatable energy/optical conduit as well as a distal end of the catheter that is capable of being oriented by an externally applied magnetic field.

However, the use of rotatable conduits was known at the time the invention was made. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Ponzi to include rotation for the purpose of increased flexibility to the system.

In addition, the use of magnetically controlled catheters for the purpose of navigating and steering a catheter through a patient's body using magnetic members in combination with an externally applied magnetic field was known at the time the invention was made. Specifically, Nevo teaches the use of magnetically controlled catheter "in order to steer the [catheter] through the body" (see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of use of the apparatus of Ponzi by applying an externally applied magnetic field

Application/Control Number: 09/777,018

Art Unit: 3743

to control the movement of the magnetic members of the catheter because it is well known in the art, as taught by Nevo, to use an externally applied magnetic field "in order to steer the [catheter] through the body".

Regarding **claim 36**, Ponzi as modified discloses that as applied to **claim 35**, as well as, a support structure **19/14/36** that has one or more magnet members (such as **72**, etc.) (recited in columns 9-10).

Regarding **claim 37**, Ponzi as modified discloses that as applied to **claim 36**, as well as, a support structure **19/14/36** that is a sheath, as shown in Figures 1-8.

Regarding **claim 38**, Ponzi as modified discloses that as applied to **claim 37**, as well as, a support structure that has an ablation tool **46** (column 8, lines 10-20).

Regarding claim 42, Ponzi discloses a device comrprsing:

a catheter 12 having a proximal end and distal end and a lumen 18 therebetween; a support structure 19/36/14 in the lumen 18 adjacent the distal end;

one or more energy/optical conduits (such as **46**, etc.) in the catheter **12**, each having a distal end supported by the support structure **19/36**; and

one or more magnet members (such as **72** with **36** and **38**) disposed in the distal end of the catheter **12** (recited throughout the specification with emphasis on column 9), as shown in Figures 2A-8.

Ponzi discloses an apparatus comprising all the limitations recited in **claim 42**, with the exception of one or more magnetic members that are positioned in the wall of the catheter or are rotatable within the catheter as well as a distal end of the catheter that is capable of being oriented by an externally applied magnetic field.

However, the magnet members of Ponzi are positioned in the wall of the tip, which can be considered an equivalent. Also, the use of rotatable magnets was known at the time the invention was made. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Ponzi to include rotation for the purpose of increased steering of the system.

In addition, the use of magnetically controlled catheters for the purpose of navigating and steering a catheter through a patient's body using magnetic members in combination with an externally applied magnetic field was known at the time the invention was made. Specifically, Nevo teaches the use of magnetically controlled catheter "in order to steer the [catheter] through the body" (see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of use of the apparatus of Ponzi by applying an externally applied magnetic field to control the movement of the magnetic members of the catheter because it is well known in the art, as taught by Nevo, to use an externally applied magnetic field "in order to steer the [catheter] through the body".

Regarding **claim 40**, Ponzi as modified discloses that as applied to **claim 39**, as well as, an ablation member **46** at the catheter distal end, as shown in Figures 1-8.

Regarding **claim 41**, Ponzi as modified discloses that as applied to **claim 40**. However, Ponzi does not recite one or more magnet members that are comprised by the support member. The electrode tip of Ponzi has the ablation laser and is considered an equivalent given the disclosure in the current specification.

Regarding **claim 42**, Ponzi as modified discloses that as applied to **claim 41**, as well as, a support structure that has a passage **78** for a guidewire (column 11, lines 65-67).

Page 8

Application/Control Number: 09/777,018

Art Unit: 3743

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

- 12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- 13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR())W July 25, 2005

Heny Bennett
Supervisory Patent Examiner